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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,750	09/06/2005	Markus Matuschek	13311-00009-US	6025

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1656

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/541,750	Applicant(s) MATUSCHEK ET AL.	
	Examiner CHIH-MIN KAM	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-33, 35-46 and 48-56 is/are rejected.
- 7) ☒ Claim(s) 13, 34 and 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/8/05; 8/18/05; 1/26/07; 2/19/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-56, ptef 1 promoter comprising SEQ ID NO:35, and the vector pBinAHygBTpTEF1-HPcrtZ comprising SEQ ID NO:37 in the response to restriction requirement filed February 6, 2008 is acknowledged. The traversal is on the ground(s) that there is no undue burden on the Examiner to search the whole invention; and that the present application relates to a method of producing carotenoids or their precursors using genetically modified organisms of the *Blakeslea* genus, and the claimed method is applicable generally to produce any type of carotenoid or its precursors, independent to the promoter used, but depending the coding sequence chosen. The inventions of all the claims share a common special technical feature, and the promoters and the vectors listed by the Examiner correspond to the species recited in the dependent claims. A requirement for a further election based on the species recited in a dependent claim is therefore improper under PCT rule. Applicants' response has been considered, regarding the promoter, the argument is persuasive, thus, the species election for different promoters is withdrawn, claims 9 and 10 will be included for examination. However, regarding the vectors, the argument is not found persuasive because of the following reasons. As indicated in the response by applicants, the claimed method is applicable generally to produce any type of carotenoid or its precursors, independent to the promoter used, but depending on the coding sequence chosen, where the coding sequence is comprised in the vectors, which would determine which carotenoid is produced in the claimed method. Thus, each vector comprising different nucleotide sequence (i.e., SEQ ID NO: 38-51 and 62) are patentably distinct species. Furthermore, co-examination of a vector comprising a nucleotide

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sequence of SEQ ID NO:38-51 and 62 would have required additional search on these nucleic acid sequences. Therefore, co-examination of these additional nucleotide sequences would require a serious additional burden of search. Thus, SEQ ID NOs:37-51 and 62 of claims 34 and 47 are withdrawn from consideration, and claims 1-56 and SEQ ID NO: 3 and 37 are examined.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claim 8 is objected to because of the use of the term “(hph”. Appropriate correction is required.
3. Claims 34 and 47 are objected to because the claim recites non-elected nucleotide sequences.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-12, 14-33, 35-46 and 48-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 1-12, 14-33, 35-46 and 48-56 are indefinite because of the use of the terms “genetically modified organisms of *Blakeslea*” and “transformation of at least one of the cells”. The terms cited render the claim indefinite, it is not clear what nucleotides or vectors are used to transform the cells in step (i) of the method of producing carotenoids or their precursors. Without citing the nucleotides or vectors in the claims, it is not clear what carotenoid or its precursor is produced. Claims 2-12, 14-33, 35-46 and 48-56 are included in the rejection

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because they are dependent on a rejected claim and does not correct the deficiency of the claim from which they depend.

6. Claim 12 is indefinite because of the use of the term “derived from”. The term cited renders the claim indefinite, it is not clear how different the *gpd* promoter and *trpC* terminator derived from *Aspergillus nidulans* are from the parent sequences. Use the term “from” or “obtained from” is suggested.

7. Claims 22-33 and 55 are indefinite because of the use of the term “highly pure”. The term cited renders the claim indefinite since it is a relative term, it is not clear what purity the term refers to, e.g., whether the term means 99% pure, or 90% pure. Claims 23-33 and 55 are included in the rejection because they are dependent on a rejected claim and does not correct the deficiency of the claim from which they depend.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-7, 9, 12, 14 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Selten *et al.* (WO 98/46772).

Selten *et al.* teach the production of genetically transformed filamentous fungi such as fungi of the *Blakeslea* genus (page 15, lines 3-21; page 16, line 6), where the genetic engineered fungi can be used to produce secondary metabolites such as carotenoids (page 27, line 9; claims 19-21) when the expression cassettes with the requisite genes including expression elements

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(e.g., a gpd promoter, a terminator) are introduced into the genome, and the genetic engineering of genome can be carried out by homologous recombination (page 19, lines 5-29; page 31; claims 5-7, 9, 12 and 14). Selten *et al.* also teach the selection and propagation of the genetically engineered cells (see claims 21 and 22 of the WO document), a method of producing metabolites (see claim 28 of the WO document; claims 1 and 3-4).

Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-12, 14-21 and 54 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12, 14-22, 31-36 and 39-41 of co-pending application 10/541,993 (based on the elected claims filed 11/2/07).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-12, 14-21 and 54 in the instant application disclose a method for producing carotenoids or their precursors using genetically modified organisms of the *Blakeslea* genus, which method comprises the following steps: (i) transformation of at least one of the cells, (ii) homokaryotic conversion of the cells obtained in step (i) to produce cells in which one or more genetic characteristics of the nuclei are all modified in an identical manner and said genetic

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modification manifests itself in the cells, (iii) selection and reproduction of the genetically modified cell or cells, (iv) cultivation of the genetically modified cells, and (v) preparation of the carotenoid produced by the genetically modified cells or the carotenoid precursor produced by said genetically modified cells. This is obvious variation in view of claims 1-12, 14-22, 31-36 and 39-41 of the co-pending application which disclose a method for producing genetically modified organisms of the *Blakeslea* genus, which method comprises the following steps: (i) transformation of at least one of the cells, and (ii) selection and reproduction of the genetically modified cell or cells, and the method may comprise an additional step of homokaryotic conversion of the cells obtained in step (i) to produce cells in which one or more genetic characteristics of the nuclei are all modified in an identical manner and said genetic modification manifests itself in the cells, between the steps of (i) and (ii) (claim 41), and the genetically modified organisms of the *Blakeslea* genus produced by the method is used to prepare carotenoids or their precursors (claim 19). Both sets of claims are directed to a method for producing genetically modified organisms of the *Blakeslea* genus, and the method may further comprise steps to produce carotenoids or their precursors. Thus, claims 1-12, 14-21 and 54 in the present application and claims 1-12, 14-22, 31-36 and 39-41 in the co-pending application are obvious variations of a method for producing genetically modified organisms of the *Blakeslea* genus, and the method may further comprise steps to produce carotenoids or their precursors.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Objections

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10. Claim 13 is objected to because the claim is dependent from a rejected claim.

Conclusion

11. Claims 1-12, 14-33, 35-46 and 48-56 are rejected; and claims 13, 34 and 47 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

CMK

April 23, 2008